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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/062,587	01/31/2002	Harvey D. Preisler	047940-0135	1948
23524	7590	01/03/2007		
FOLEY & LARDNER LLP 150 EAST GILMAN STREET P.O. BOX 1497 MADISON, WI 53701-1497			EXAMINER CANELLA, KAREN A	
			ART UNIT 1643	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE			MAIL DATE	DELIVERY MODE
3 MONTHS			01/03/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/062,587	<b>Applicant(s)</b> PREISLER, HARVEY D.	
	<b>Examiner</b> Karen A. Canella	<b>Art Unit</b> 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☐ Claim(s) 1,3-21,33,55-75,82,85 and 88-99 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 1,3-21 and 33 is/are allowed.
- 6) ☐ Claim(s) 55-75,82,85,88-90,93 and 95-99 is/are rejected.
- 7) ☐ Claim(s) 91,92 and 94 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |  |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>6/11/2002</u> . | 6) <input type="checkbox"/> Other: ____  |

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on Oct 10, 2006 has been entered.

Claims 76-81, 83, 86, 87 have been canceled. Claims 91-99 have been added. Claims 55, 56, 73, 74, 75, 82, 85, 88-90 have been amended. Claims 1, 3-21, 33, 55-75, 82, 85, 88-99 are pending and under consideration.

Sections of Title 35, U.S. Code not found in this action can be found in a prior action.

Claims 55-75, 82, 85, 88-90, 93, 95-99 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 55-62, 73-82, 85 and 98 are drawn to isolated polypeptides which minimally comprise variants of SEQ ID NO:1, 2, 3, 16 and 22 having one or more conservative amino acid substitution, wherein the polypeptide binds to acute myeloid leukemia cells and induced differentiation of acute myeloid leukemia cells into mature blood cells. It is noted that only one variant was described by the specification, that of SEQ ID NO:8, wherein the Arg at residue 6 of SEQ ID NO:3 which is residue 7 of SEQ ID NO:7 is substituted with Aln. Claims 88-90, 93, 95-97 and 99 are drawn to isolated polypeptides minimally comprising variants of SEQ ID NO: 26-31 having one or more conservative amino acid substitution, wherein the polypeptide binds to normal bone marrow cells, but not to acute leukemia cells.

The instant rejected claims encompass two structurally diverse sets of peptides, because said peptides need not have any structural resemblance to the disclosed SEQ ID NO:1, 2, 3, 16 and 12, or 26-31, because the claims permit all the residues to have conservative substitutions,

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and thus permit peptides which do not retain any sequence identity to SEQ ID NO:1, 2, 3, 16 and 12, or 26-31 to be included in the claimed genus based on functional activity alone. It is noted that claim 55 does not specify a specific antigen on the acute myeloid leukemia cells and claim 88 does not specify a specific antigen on the normal bone marrow cells to which binding of the peptides is directed. Thus the instant claims encompassing variant peptides may bind the acute myeloid leukemia cells or normal bone marrow cells at completely different antigens than the disclosed peptides of SEQ ID NO:1, 2, 3, 16 and 12, or 26-31. Thus the claimed genus of variant peptides is highly variant with respect to the antigens bound on the targeted cells, as well as the primary sequences of the binding polypeptides. One of skill in the art would reasonably conclude that applicant was not in possession of the genus of polypeptides characterized by "one or more conservative amino acid substitutions" and having the claimed function of binding to AML cells and inducing differentiation thereby, or binding to normal bone marrow, but not to AML cells because of the huge genus of targeted antigens included the surface of either the AML cell or the normal bone marrow.

Claims 1, 3-21, 33 are free of the art. Claims 91, 92 and 94 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

All other objections and rejections as set forth or maintained in the previous Office action are withdrawn in light of applicants amendments.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10-6:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571)272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Karen A Canella, Ph.D.

12/26/2006

  
KAREN A. CANELLA PH.D.  
PRIMARY EXAMINER